

### **REMARKS**

Applicant appreciates the Examiner's thorough examination of the subject application and requests reconsideration of the subject application based on the following remarks.

Claims 1, 2 and 5-37 are pending in the subject application. Claims 1, 16, 19, 25, 26, 34, 36 and 37 have been amended for clarification purposes. Support for the amendments to claims 1, 16, 19, 25, 26, 34, 36 and 37 is found throughout the Specification, as filed, and no new matter is presented by the amendment.

Claims 1, 2, 5-6, 7-25, 33, 34-36 stand rejected under 35 U.S.C §102(b) as being anticipated by Anderson (795). Claims 26-32 and 37 stand rejected under 35 U.S.C. 103(a) as obvious over the Harada patent. Claims 1-5 and 20-28 stand rejected under 35 U.S.C. 103(a) as unpatentable over Anderson (795) in view of Gleason.

Favorable reconsideration in light of the amendments and remarks which follow s respectfully requested.

#### 1. 35 U.S.C. §102 Rejections

Claims 1, 2, 5-6, 7-25, 33, 34-36 have been rejected under 35 U.S.C §102(b) over Anderson. In particular, the Office asserts:

Anderson (795) discloses a method and apparatus showing the positioning of the body portion (umbilical cord) within a curved shield member (21) of medical grade material (Co. 4, lns. 51-55), and inserting an insertion member into the umbilical cord to extract blood (Col. 5, lns. 21-67) in the form of a hollow needle (73). The step of stabilizing the body portion with a digit, (Col. 3 at line 10-12) is disclosed. Regarding claim 11, the withdrawal step and the removing the body portion of obvious steps that the physician would take to complete the process.

Applicants respectfully traverse. Applicants claim, in amended claims 1, 16, 19, 25, 34 and 36 a method and device for collection of blood, particularly umbilical cord blood. Applicants device comprises a shield member/cradle member in which the body member (umbilical cord) is received. Applicants device is further devoid of any fastening means that would fasten the umbilical cord to the shield member/cradle

member. According to Applicants' method for collecting blood, the umbilical cord is placed in the shield member/cradle member and the user stabilizes the umbilical cord within the shield member/cradle member solely using his or her digit. This is a significant advantage in that Applicants' device is very simple in design and, thus, inexpensive and easy to manufacture and very easy to use. To use the device, a user simply places the umbilical cord in the shield member/cradle member, uses a finger to secure the cord, and withdraws blood. The umbilical cord can then be released from the shield member/cradle member by simply releasing the user's finger from the cord. This is a very simple and quick procedure, which is of great importance in a medical procedure such as that involved when delivering one or more babies. The collection of the blood can occur in minimal time using a very simple procedure.

This is unlike the device described by Anderson. Anderson describes a complex device wherein a trough 21 receives the umbilical cord and wherein umbilical cord clamps 26, 32 located on opposite ends of the trough 21 clamp and restrict the umbilical cord. Thus, the device described by Anderson includes complex clamps that require additional time and expense to manufacture and assemble. These clamps must be subjected to some type of a quality control to ensure that they operate properly and, thus, there is a possibility that defective clamps can be produced. This all requires additional time, materials and expense. Further, the use of the device in accordance with Anderson is also more complicated and time consuming than Applicants'. Using Anderson's device and methods, a cord must be inserted into the trough. The cord must be inserted more precisely in the trough such that one end of the umbilical cord (cut end) reaches the clamp so that it can be fastened. The clamps must then be manipulated to fasten the umbilical cord. The blood is withdrawn and the clamps must then be unfastened to release the umbilical cord. As set out above, the speed and simplicity of a medical procedure such as that involved here is of great importance and Anderson's device requires additional time to use and involves a more complex procedure than that taught by Applicant.

As provided in MPEP-2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegel Bros. v. Union Oil Co. of California*, 2 USPQ2d

1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identify of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

It is clear from the foregoing remarks that the above-identified claims are not anticipated by the Anderson reference. Anderson does not describe each and every element of Applicants' claims.

Further, Applicants respectfully submit that Applicants' method would not be inherent in the Anderson device. In particular, the device of Anderson would not be used in a manner wherein the digit of a user's hand solely fastens the umbilical cord to the trough. As set out in Anderson, the described device is specifically designed with a complex procedure in mind wherein the cord is clamped in place and various valves are opened and closed to allow for the automatic withdrawal of the placental blood, mixture of the blood with an anticoagulant, and storage of the mixture in a storage bag.

Applicants respectfully submit that there is no suggestion or motivation to modify the Anderson description so as to comply with Applicants' teaching. Further, such a modification would render the device of Anderson ineffective in carrying out the complex procedure that the device of Anderson was specifically designed for.

Accordingly, claims 1, 16, 19, 25, 34 and 36 are not anticipated by Anderson. Claims 2, 5-6, 7-24, 33 and 35 depend from claims 1, 16, 19, 25, 34 and 36 and, likewise, are not anticipated by Anderson.

## 2. 35 U.S.C. §103 Rejections

Claims 26-23 and 37 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson (795) in view of Gleason. In particular, Gleason is cited for describing the use of a blood collection/sampling device in a kit.

Applicants respectfully traverse for the reasons set forth above. Namely, Anderson does not describe or suggest a blood collection device comprising a shield member/cradle member for receiving a body member (umbilical cord) shield member/cradle member does not include any fastening mechanism for fastening the umbilical cord within the shield member/cradle member. Further Anderson does not describe or suggest a method wherein the umbilical cord is placed within the shield member/cradle member and wherein the umbilical cord is solely secured in the shield member/cradle member using the user's digit. Rather, Anderson specifically requires clamps for clamping portions of the umbilical cord to the trough and specifically requires that these claims be used as such.

Gleason is cited for describing the use of a blood collection/sampling device in a kit and does not remedy the deficiencies of Anderson set forth above.

Accordingly, claims 1, 16, 19, 25, 26, 34, 36 and 37 are patentable over Anderson in view of Gleason. Claims 2, 5-15, 17-18, 27-33 and 35 depend from claims 1, 16, 19, 25, 26, 34, 36 and 37 and, likewise, are patentable over Anderson in view of Gleason

### **CONCLUSION**

Reconsideration and allowance of claims 1, 2 and 5-37 is respectfully requested in view of the foregoing discussion. This case is believed to be in condition for immediate allowance. Applicant respectfully requests early consideration and allowance of the subject application.

Applicants believe that no extension of time is required since this response is being filed before the expiration of the specified time period. Applicants, however, conditionally petition for an extension of time to provide for the possibility that such a petition has been inadvertently overlooked and is required. As provided below charge Deposit Account No. **04-1105** for any required fee.

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

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Respectfully submitted,



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Lisa Swiszczy Hazzard (Reg. No. 44,368)  
Dike, Bronstein, Roberts & Cushman  
Intellectual Property Group of  
EDWARDS & ANGELL, LLP  
P.O. Box 9169  
Boston, MA 02209  
Tel. No. (617) 517-5512